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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/380,336 11/23/99 HOFSTRAAT J AEM2527PIUS

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HM12/0119

EXAMINER

GABEL, G

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

01/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/380,336

Applicant(s)

HOFSTRAAT, JOHANNES
WILLEM

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

Preliminary Amendment Entry

1. The preliminary amendment filed 11/23/99 is acknowledged and has been entered. Claims 1 and 3-6 have been amended. Claims 7-9 have been added. Claims 1-9 are pending and under examination.

Information Disclosure Statement

2. The Information Disclosure Statement (PTO-1449) filed 1/6/00 in Paper No. 6 is acknowledged. The foreign patent documents 9704001-0 (Brazil), 1340087 (U.S.S.R.), and 1621720 (U.S.S.R.) were not considered because neither an English translation nor a statement of relevancy was provided therefor.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in failing to recite active positive method steps. Claim 1 appears to intend a method claim but the limitations recited: "a specific binding

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partner..., an immunoreactant provided with a label... and a ligand..." appear to enumerate specific elements of a product.

Claim 1 is indefinite in using parenthetical symbols, i.e. (immuno) because it is unclear as to whether the limitation within the parenthesis is part of the claim. See also claim 5.

Claim 1 is vague, confusing, and indefinite in reciting "an immunoreactant provided with a label wherein the label is a lanthanide ion-ligand complex" because it is unclear what is encompassed by the term "provided" as used in the claim. Specifically, it is unclear as to whether the "immunoreactant" is an element, i.e. another binding partner, that is *conjugated* to a label or the immunoreactant itself *comprises/consists of* a label. See also claim 5.

Claim 1 is confusing in reciting "the ligand comprises or is in contact with a sensitizing moiety" because it is unclear how the ligand can (both) comprise or contact with a sensitizing moiety. Please clarify. See also claim 5.

Claim 3 is indefinite in using parenthetical symbols because it is unclear as to whether the limitation within the parenthesis is part of the claim.

Regarding claim 3, the term "derivatives" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "derivatives"), thereby rendering the scope of the claim unascertainable. See MPEP § 2173.05(d). See also claims 4 and 7.

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Claim 4 is vague and indefinite in reciting "the ligand is a composition comprising a compound comprising" because it is unclear how the ligand can be both a composition or a compound in the claim.

Claim 4 has improper antecedent basis problem in reciting "a sensitizing moiety".

Claim 4 is indefinite in using parenthetical symbols because it is unclear as to whether the limitation within the parenthesis is part of the claim.

Claim 5 is indefinite in using parenthetical symbols because it is unclear as to whether the limitation within the parenthesis is part of the claim.

Claim 6 is vague and indefinite in reciting the term "suitable" because the term "suitable" is a subjective term that lacks a comparative basis for defining its metes and bounds. See also claim 9.

Claim 9 has improper antecedent basis problem in reciting "An apparatus as claimed in claim 6".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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4. Claims 1-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Kardos et al (US 6,159,686).

Kardos et al disclose methods and apparatus for performing sensitive detection of analytes by contacting the sample with an immunoreactant (directly labeled analyte binding reagent, i.e. antibody) provided with a label (linked to an upconverting phosphor) and a specific binding partner for the analyte (an indirectly labeled analyte binding reagent, i.e. a primary antibody that is detected by a labeled second antibody) (see column 20, lines 54-65). The immunoreactant includes antigenic epitopes, immunoglobulin, polynucleotide, streptavidin, and protein A (see column 10, lines 34-51). Upconverting labels convert long wavelength excitation radiation, i.e. near infrared, to emitted radiation (see column 5, lines 31-39, and column 11, lines 11-25). The label comprises a lanthanide ion complexed with a ligand (chelate compound) (see column 10, lines 25-27 and 30-34) and the lanthanide phosphor particles may be coated with polycarboxylic acid (see column 13, lines 5-7). The lanthanide ions include erbium and neodymium (see column 29, lines 51-53). The ligand compounds or chelates which comprise a sensitizing moiety for use as upconverting phosphors include polyaminocarboxylic acids such as ethylenediaminetetraacetic acid (EDTA) and diethylenetriaminepentaacetic acid (DTPA) (see column 29, lines 30-40). Alternatively, the sensitizing moiety may also include upconverting organic dyes such as cyanine, phthalocyanine, rhodamine, acridine, oxazine and derivatives thereof which absorb in the 400-1000 nm region (see column 30, lines 20-49). The apparatus includes an

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excitation light source including near infrared (pump) laser and a suitable detector such as a photodiode (see columns 31-32). Kardos et al. disclose packaging the compositions comprising upconverting labels and reagents for use in the assay in a kit formation (see column 48, lines 27-39).

5. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(e) as being inherently anticipated by Wieder et al. (US 5,830,769).

Wieder et al. disclose a homogeneous assay method for detecting an analyte in a test sample wherein the sample is contacted with a lanthanide ion-ligand complex coupled with an immunoreactant and comingled with a specific binding partner and wherein interligand energy transfer takes place in the binding reaction (see columns 3-4 and 8). Wieder et al. specifically teach a lanthanide ion (rare earth metal) complexed with a ligand wherein the ligand is a member of a specific binding capable of forming a changed fluorescence chelate with the lanthanide ion (see column 4, lines 5-23). The lanthanide ion includes neodymium (Nd_{3+}) and erbium (Er_{3+}) (see column 5, lines 13-17). The ligands useful as chelate includes polyaminocarboxylic acid, pyridinedicarboxylic acid, and derivatives thereof (see column 5, line 18 to column 6, line 64). The chelate forming ligand is the site for linking to specific binding partners (biospecific groups) that specifically recognize or immunologically react with another molecular species such as antibodies and antigens, hormones and receptors etc. (see column 7, lines 51-65). Wieder et al. further disclose including a sensitizing moiety to enhance or quench the

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fluorescence of the chelate which includes rhodamines, fluoresceins, and phycobiliproteins (see column 9, lines 9-60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5-6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wieder et al. (US 5,830,769) in view of Kardos et al (US 6,159,686).

Wieder et al. has been discussed supra. Wieder et al. differ in failing to teach incorporating the compositions comprising immunoreactants, labels, and reagents in a kit formation. Wieder et al. further differ in failing to teach an apparatus comprising a light source and detector for detecting luminescence in the 800-1600 nm range.

Kardos et al. has been discussed supra.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate all the immunoreactants and labels taught by Wieder et al. into a kit format such as taught by Kardos because kit formations are conventional and well known for their recognized advantage of convenience and economy.

Further, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use an apparatus comprising near infrared laser and its

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corresponding detector such as taught by Kardos into the method of Wieder to measure fluorescence emissions from binding reactions between analyte and binding partners because Wieder teaches the same elements and organic dyes/sensitizing moieties as those taught by Kardos which absorb in the 400-1000 nm range and therefore an apparatus with the same excitation light source and suitable photodiode detector thereto such as taught by Kardos is suitable for performing the same in the method of Wieder.

7. No claims are allowed.

Remarks

8. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

Selvin et al. (US 5,656,433) disclose lanthanide ions that form high affinity complexes with ligands to form lanthanide ion-ligand complexes then coupled with immunoreactants to create specific label or reagent wherein the ligand includes a sensitizing moiety such as rhodamine, fluorescein, coumarin, and derivatives thereof.

Zarling et al. (US 5,891,656) disclose up-converting labels for biological and other assays using laser excitation techniques.

Selvin et al. (WO 96/00901) disclose lanthanide chelators covalently joined to coumarin-like sensitizer which are coupled to other compounds to create specific labels and reagents in assays utilizing resonance energy transfer.

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Vallarino et al. (US 5,696,240) disclose macrocyclic complexes of Yttrium, the lanthanides and the actinides having peripheral coupling functionalities.

Diamandis (US 5,312,922) discloses europium and terbium which form highly fluorescent complexes fluoregenic chelators.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday, 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gailene R. Gabel
Patent Examiner
January 16, 2001



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